



JC14 Res'd PCT/PTO 31 AUG 2001

PCT

Sim & McBurney

Patent and Trade-mark Agents

Please Quote
Our ref. 1038-1138 MIS

Your ref.

Writer's Ext. 239

E-mail: mistewart@sim-mcburney.com

August 30, 2001

VIA COURIER

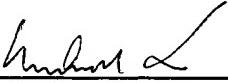
The Commissioner of Patents
and Trademarks
Washington, D.C. 20231
United States of America

Dear Sirs:

RE: U.S. Patent Application No. 09/806,709
Filing Date: October 7, 1999
Applicant: Connaught Laboratories Limited
PROTECTIVE RECOMBINANT HAEMOPHILUS INFLUENZAE
HIGH MOLECULAR WEIGHT PROTEINS

Please find enclosed an Information Disclosure Statement and copies of the references listed therein with respect to each of the references cited in the specification, in the International Search Report received on the corresponding International application and in prior U.S. application No. 09/806,709. The items indicated by asterisks will follow shortly.

Respectfully submitted,



Michael I. Stewart
Registration No. 24,973

M.I. Stewart/ac
Encl.

330 University Avenue
6th floor
Toronto, Canada
M5G 1R7
Telephone (416) 595-1155
Fax (416) 595-1163

MICHAEL I STEWART
ROGER T. HUGHES, Q.C.
TONI POLSON ASHTON
JOHN H. WOODLEY
KENNETH D. MCKAY
TIMOTHY M. LOWMAN
STEPHEN M. LANE
ARTHUR B. RENAUD
STEPHEN J. PERRY
PATRICIA A. RAE
DAVID A. RUSTON
L.E. TRENT HORNE
LOLA A. BARTOSZEWCZ
THOMAS T. RIEDER
WARREN J. GALLOWAY
STEVEN L. NEMETZ
URSULA M. MCGUINNESS
ROBERT C.T. LIANG
SENIOR CONSULTANTS
PETER W. MCBURNEY
BRENDA L. BOARDMAN
TECHNICAL ASSISTANTS
KIMBERLY A. MCMANUS, PH.D.
PETER S. HARRISON, PH.D.
LESLEY M. MORRISON, B.Sc. MECH.
GEOFFREY B.C. DE KLEINE, M.Sc. (ENG.)
WENDY M. NOSS, B.A., L.L.B.

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1038-1138 MIS:ac	SERIAL NO. 09/806,709
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT: Sheena Loosmore et al.	
		FILING DATE October 7, 1999	GROUP ---

O I P E
PATENT & TRADEMARK OFFICE
AUG 31 2001

U.S. PATENT DOCUMENTS

*INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCL.	FILING DATE
	4,496,538	Jan/85	Gordon	424	92	
*	5,603,938	Feb/97	Barenkamp	424	256.1	
	5,194,254	Mar/93	Barber et al.	424	85.8	
	5,506,139	Apr/96	Loosmore et al.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCL.	TRANSLATION
	WO 97/36914	Oct/97	PCT			YES NO
	WO 92/17167	Oct/92	PCT			
	WO 94/21290	Sep/94	PCT			
	WO 93/19090	Sep/93	PCT			
	0 502 637 A1	Feb/92	EP			
	Supplement No. 2	Nov/98	EPO			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	Berkowitz et al. 1987. J. Pediatr. 110 :509.		
2	Claesson et al. 1989. J. Pediatr. 114 :97.		
3	Black, S.B., H.R. Shinefield, B. Fireman, R. Hiatt, M. Polen, E. Vittinghoff, The Northern California Kaiser Permanent Vaccine Study Center Pediatrics Group. Efficacy in infancy of oligosaccharide conjugate <i>Haemophilus influenzae</i> type b (HbOC) vaccine in a United States population of 61,080 children. 1991. Pediatr. Infect. Dis. J. 10 :97-104.		
4	Madore, D.V. 1996. Impact of immunization on <i>Haemophilus influenzae</i> type b disease. Infectious Agents and Disease 5 :8-20.		
5	Bluestone, C.D. 1982. Current concepts in otolaryngology. Otitis media in children: to treat or not to treat? N. Engl. J. Med. 306 :1399-1404.		
EXAMINER:		DATE CONSIDERED:	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT BY APPLICANT	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1038-1138 MIS:ac	SERIAL NO. 09/806,709
APPLICANT: Sheena Loosmore et al.			
FILING DATE October 7, 1999			
GROUP ---			

AUG 3 1 2001
PATENT & TRADEMARK OFFICE

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
6	Barenkamp, S.J., and F.F. Bodor. 1990. Development of serum bactericidal activity following nontypable <i>Haemophilus influenzae</i> acute otitis media. <i>Pediatr. Infect. Dis.</i> 9 :333-339.		
7	Barenkamp, S.J., and E. Leininger. 1992. Cloning, expression, and DNA sequence analysis of genes encoding nontypeable <i>Haemophilus influenzae</i> high-molecular-weight surface-exposed proteins related to filamentous hemagglutinin of <i>Bordetella pertussis</i> . <i>Infect. Immun.</i> 60 :1302-1313.		
8	Barenkamp, S.J., and J.W. St. Geme III. 1994. Genes encoding high-molecular-weight adhesion proteins of nontypeable <i>Haemophilus influenzae</i> are part of gene clusters. <i>Infect. Immun.</i> 62 :3320-3328.		
9	St. Geme III, J.W. and S. Grass. 1998. Secretion of the <i>Haemophilus influenzae</i> HMW1 and HMW2 adhesins involves a periplasmic intermediate and requires the HMWB and HMWC proteins. <i>Molec. Microbiol.</i> 27 :617-630.		
10	St. Geme III, J.W., S. Falkow, and S.J. Barenkamp. 1993. High-molecular-weight proteins of nontypeable <i>Haemophilus influenzae</i> mediate attachment to human epithelial cells. <i>Proc. Natl. Acad. Sci. USA</i> 90 :2875-2879.		
11	Barenkamp, S.J. 1996. Immunization with high-molecular-weight adhesion proteins of nontypeable <i>Haemophilus influenzae</i> modifies experimental otitis media in chinchillas. <i>Infect. Immun.</i> 64 :1246-1251.		
12	Tabor, S., and C.C. Richardson. 1985. A bacteriophage T7 RNA polymerase/promoter system for controlled exclusive expression of specific genes. <i>Proc. Natl. Acad. Sci. USA</i> 82 :1074-1078.		
13	Patient, M.E., and D.K. Summers. 1993. ColE1 multimer formation triggers inhibition of <i>Escherichia coli</i> cell division. <i>Molec. Microbiol.</i> 9 :1089-1095.		
14	Barenkamp, S. 1986. Protection by serum antibodies in experimental nontypeable <i>Haemophilus influenzae</i> otitis media. <i>Infect. Immun.</i> 52 :572-578.		
15	Yang, Y.-P., S.M. Loosmore, B. Underdown, and M.H. Klein. 1998. Nasopharyngeal colonization with nontypeable <i>H. influenzae</i> in chinchillas. <i>Infect. Immun.</i> 66 :1973-1980.		
16	Fleischmann et al. 1995. Whole-genome random sequencing and assembly of <i>Haemophilus influenzae</i> Rd. <i>Science</i> 269 :496-512.		
17	O'Hagan, DT. 1992. Oral delivery of vaccines. Formulation and clinical pharmacokinetic considerations. <i>Clin. Pharmacokinet</i> 22 (t): 1-10.		
18	Ulmer et al. 1993. <i>Curr. Opinon Invest. Drugs</i> 2 :983-989.		
19	Lockhoff, O., 1991. Glycolipids as immunomodulators: Synthesis and properties.		
20	Nixon-George A., et al., 1990. The adjuvant effect of stearyl tyrosine on a recombinant subunit hepatitis B surface antigen. <i>J. Immunol</i> 144 (12):4798-4802.		
21	Dawid S.R. et al., 1998, High Molecular Weight p. 74 XP-002133638		
22	St. Geme III W.J. et al., Infection and Immunity (1998), p. 364-368.		
23	Yamanaka N. and Faden H. The Journal of Pediatric, 1993; 122 : 212-218.		
24	Murphy F.T. et al., <i>Pediatric Infect Dis J.</i> 1989; 8 :S66-S68		
EXAMINER:		DATE CONSIDERED:	

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT BY APPLICANT	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE OCT 1 2001 PATENT & TRADEMARK OFFICE U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO. 1038-1138 MIS:ac	SERIAL NO. 09/806,709
		APPLICANT: Sheena Loosmore et al.	
		FILING DATE October 7, 1999	GROUP ---

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
6	Barenkamp, S.J., and F.F. Bodor. 1990. Development of serum bactericidal activity following nontypable <i>Haemophilus influenzae</i> acute otitis media. <i>Pediatr. Infect. Dis.</i> 9 :333-339.		
7	Barenkamp, S.J., and E. Leininger. 1992. Cloning, expression, and DNA sequence analysis of genes encoding nontypeable <i>Haemophilus influenzae</i> high-molecular-weight surface-exposed proteins related to filamentous hemagglutinin of <i>Bordetella pertussis</i> . <i>Infect. Immun.</i> 60 :1302-1313.		
8	Barenkamp, S.J., and J.W. St. Geme III. 1994. Genes encoding high-molecular-weight adhesion proteins of nontypeable <i>Haemophilus influenzae</i> are part of gene clusters. <i>Infect. Immun.</i> 62 :3320-3328.		
9	St. Geme III, J.W. and S. Grass. 1998. Secretion of the <i>Haemophilus influenzae</i> HMW1 and HMW2 adhesins involves a periplasmic intermediate and requires the HMWB and HMWC proteins. <i>Molec. Microbiol.</i> 27 :617-630.		
10	St. Geme III, J.W., S. Falkow, and S.J. Barenkamp. 1993. High-molecular-weight proteins of nontypeable <i>Haemophilus influenzae</i> mediate attachment to human epithelial cells. <i>Proc. Natl. Acad. Sci. USA</i> 90 :2875-2879.		
11	Barenkamp, S.J. 1996. Immunization with high-molecular-weight adhesion proteins of nontypeable <i>Haemophilus influenzae</i> modifies experimental otitis media in chinchillas. <i>Infect. Immun.</i> 64 :1246-1251.		
12	Tabor, S., and C.C. Richardson. 1985. A bacteriophage T7 RNA polymerase/promoter system for controlled exclusive expression of specific genes. <i>Proc. Natl. Acad. Sci. USA</i> 82 :1074-1078.		
13	Patient, M.E., and D.K. Summers. 1993. ColE1 multimer formation triggers inhibition of <i>Escherichia coli</i> cell division. <i>Molec. Microbiol.</i> 9 :1089-1095.		
14	Barenkamp, S. 1986. Protection by serum antibodies in experimental nontypeable <i>Haemophilus influenzae</i> otitis media. <i>Infect. Immun.</i> 52 :572-578.		
15	Yang, Y.-P., S.M. Loosmore, B. Underdown, and M.H. Klein. 1998. Nasopharyngeal colonization with nontypeable <i>H. influenzae</i> in chinchillas. <i>Infect. Immun.</i> 66 :1973-1980.		
16	Fleischmann et al. 1995. Whole-genome random sequencing and assembly of <i>Haemophilus influenzae</i> Rd. <i>Science</i> 269 :496-512.		
17	O'Hagan, DT. 1992. Oral delivery of vaccines. Formulation and clinical pharmaco kinetic considerations. <i>Clin. Pharmacokinet</i> 22 (1): 1-10.		
18	Ulmer et al. 1993. <i>Curr. Opinion Invest. Drugs</i> 2 :983-989.		
19	Lockhoff, O., 1991. Glycolipids as immunomodulators: Synthesis and properties.		
20	Nixon-George A., et al., 1990. The adjuvant effect of stearyl tyrosine on a recombinant subunit hepatitis B surface antigen. <i>J. Immunol</i> 144 (12):4798-4802.		
21	Dawid S.R. et al., 1998, High Molecular Weight p. 74 XP-002133638		
22	St. Geme III W.J. et al., <i>Infection and Immunity</i> (1998), p. 364-368.		
23	Yamanaka N. and Faden H. <i>The Journal of Pediatric</i> , 1993; 122 : 212-218.		
24	Murphy F.T. et al., <i>Pediatric Infect Dis J.</i> 1989; 8 :S66-S68		
EXAMINER:		DATE CONSIDERED:	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.

* Will follow shortly